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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/055,789	01/18/2002	Lijun Wu	1855.1063-010	9077

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EXAMINER	
ULM, JOHN D	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 04/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/055,789	WU ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/14/02, 1/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HL

1) Claims 1 to 45 are pending in the instant application.

2) Claims 9, 10 and 45 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A properly dependent claim cannot conceivably be infringed without infringing any of the claims from which it depends. See M.P.E.P. 608.01(n)III.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3) Claims 7 to 10 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2 to 5 of prior U.S. Patent No. 6,488,930. This is a double patenting rejection.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101, which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

4) Claims 1 to 12 and 39 to 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 to 64 of U.S. Patent No. 6,488,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims fully encompass (anticipate) the patented subject matter.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5) Claims 4, 7 to 10, 12, 18, 20, 21, 23, 27, 29, 38, 44 and 45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims expressly require the biological material recited therein as 1G1 and 2B10, which are described on page 13 of the instant specification in terms of deposited

materials. Applicant, their assignee or their agent needs to provide a declaration containing the following:

The identification of the declarant.

A statement that a deposit has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

A statement that the deposited material has been accorded a specific, recited, accession number.

A statement that the material has been deposited under conditions that assure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 37 C.F.R. 1.14 and 35 U.S.C. § 122.

A statement that the deposited material will be maintained with all of the care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case, for a period of at least thirty years after the date of deposit or for the enforceable life of the patent, whichever period is longer.

A statement by declarant that all statement made therein of declarant's knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Alternately, it may be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (e.g., see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession

number) number, name and address of the depository, and the complete taxonomic description.

6) Claims 4, 12, 18, 20, 21, 23, 27, 29 and 38 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention. These claims encompasses an antibody which has "an epitopic specificity which is the same as" "or similar to" that of 1G1, 2B10 or 10E4. The instant specification discloses that the monoclonal antibodies 1G1 and 2B10 were generated against whole cells that over-expressed an entire human CCR4 protein. The specification does not identify that portion of the human CCR4 protein to which either one of these monoclonal antibodies binds. Because the instant specification does not disclose the epitope to which 1G1 or 2B10 binds, an artisan cannot produce an antibody with the same binding specificity.

7) Claims 4, 12, 18, 20, 21, 23, 27, 29 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite in the recitation of the term "similar to", which encompasses an almost limitless number of subjective interpretations.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8) Claims 1 to 3, 5, 6, 11, 13 to 17, 19, 22, 24 to 26, 28, 30 to 37 and 39 to 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Power et al. publication (J. Biol. Chem. 270(33):19495-19500, 18 Aug. 1995) in view of the Chuntharapai et al. publication (Methods in Enzymology 288:15-27, 1997). Figure 1 on page 19497 of the Power et al. publication described an isolated cDNA encoding a human chemokine receptor for MIP-1α, RANTES, and MCP-1, and the receptor protein encoded thereby. The receptor protein of Powers et al. is a human CCR4 protein of the instant invention, as disclosed in the second paragraph on page 2 of the instant specification. Figure 2 on page 19498 of Power et al. disclosed that the chemokine receptor described therein belong to a known family of related receptors which included human interleukin-8 receptor A (Hil8ra) and human interleukin-8 receptor B (Hil8rb). The Power et al. publication does not anticipate the instant claims because it did not describe blocking antibodies to the chemokine receptor described there.

The Chuntharapai et al. publication is a review article that described the "Generation of Monoclonal Antibodies to Chemokine Receptors". This publication expressly taught that "monoclonal antibodies (MAbs) that are specific to each receptor and/or that block the ligand to a particular receptor would be extremely useful for understanding the biology of each ligand and the distribution and regulation of its

receptor expression". Because the Chuntharapai et al. publication provided both the motivation and guidance needed to produce blocking antibodies to chemokine receptors like that of Power et al., an artisan would have found it *prima facie* obvious to produce blocking monoclonal antibodies to the chemokine receptor of Power et al. by employing those methods of Chuntharapai et al. publication to facilitate the understanding of the actions of MIP-1α, RANTES, and MCP-1 on that receptor. Because Figure 2 of the Power et al. publication taught the close relationship of the receptor described there to Human interleukin receptor A and Human interleukin receptor B and the methods of Chuntharapai et al. were exemplified by the production of blocking monoclonal antibodies to each of these two IL-8 receptors an artisan had more than a reasonable expectation that the methods of Chuntharapai et al. would be readily applicable to the production of blocking monoclonal antibodies to the chemokine receptor that was described by Power et al. prior to the making of the instant invention. Further, one would have found it obvious to administer such an antibody to an individual to inhibit "the recruitment of basophils to inflammatory sites and the subsequent release of mediators such as histamine and peptidoleukotrienes" in view of the text in the first paragraph on page 19495 of Power et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).